(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 471 135 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **90870129.5**

(51) Int. Cl.5: **A61K 7/06**

(22) Date of filing: **14.08.90**

(43) Date of publication of application:
19.02.92 Bulletin 92/08

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

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(54) Compositions, medicaments and methods for the promotion of hair growth.

(57) Compositions, medicaments and methods for the promotion of hair growth are disclosed. These compositions and medicaments are comprised of either local anesthetics of the secondary or tertiary amino type or niacin. The preferred secondary and tertiary amino compounds include those which are esters of para-aminobenzoic acid, esters of Benzoic acid, esters of meta-amino benzoic acid, amides, ethers, and ketones. The preferred compositions and medicaments include either procaine hydrochloride or niacin in propylene glycol carrier. The disclosed compositions and medicaments may be topically applied to a scalp in need thereof by an eyedropper or other suitable means.

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Field of the Invention

The present invention is directed to compositions, medicaments and methods for promoting the activity of the hair follicles of a living organism and, in particular, to compositions, medicaments and methods for the treatment of the hair follicles of a human scalp to promote the growth of hair thereon.

Background of the Invention

At birth the average human scalp has approximately 100.000 - 150.000 hair follicles. Initially, hair follicles normally exhibit fine lanugo hair shafts, which are commonly referred to as "baby hair". This lanugo hair "matures", eventually, into terminal hair shafts, which is the hair most often exhibited during adolescence and adulthood. Thereafter, this terminal hair may remain as such, or it may develop into non-terminal vellus hair, which is commonly referred to as a "thinning" of the hair and, in more advanced stages, baldness.

The precise mechanism that triggers the development of non-terminal vellus hair is not precisely understood or agreed upon. However, there have been numerous attempts to provide an effective safe prophylaxis to arrest development of non-terminal vellus hairs and even to stimulate the regeneration of these vellus hairs into terminal hair shafts. Unfortunately, none of these attempts have proven to be fully satisfactory.

Thus, it can be seen that there remains a need for compositions, medicaments and methods for administering the same, which are effective in stimulating the development of terminal hairs from non-terminal vellus hairs, are safe for use with a human host, and which are easy to administer.

Summary of the Invention

Accordingly, it is a primary object of the present invention to alleviate the disadvantages and deficiencies of the prior art by providing compositions and medicaments that are effective for stimulating the development (growth) of terminal hairs from the hair bulb of non-terminal vellus hair follicles.

It is another primary object of the present invention to provide compositions and medicaments which may safely be used with a human host.

It is still another primary object of the present invention to provide methods for stimulating the development (growth) of terminal hairs from the hair bulb of non-terminal vellus hair follicles.

It is still yet another primary object of the present invention to provide methods of safely administering the compositions and medicaments to a human host.

It is a further object of the present invention to provide such compositions, medicaments and methods for the administration thereof, which are easy to perform.

In accordance with the teachings of the present invention, there is disclosed the use of a secondary or a tertiary amino local anesthetic for the manufacture of a topical medicament for stimulating the growth of a hair bulb of a vellus hair follicle.

Preferably, the secondary or tertiary amino local anesthetic is either a secondary or tertiary amino ester of para-aminobenzoic acid, or a secondary or tertiary amino type ester of either benzoic acid or meta-aminobenzoic acid, or a secondary or tertiary amino type amide or a secondary or tertiary amino type ether, or a secondary or tertiary amino type ketone.

In further accordance with the teachings of the present invention, there is disclosed the use of niacin for the manufacture of a topical medicament for stimulating the growth of a hair bulb of a vellus hair follicle.

In another aspect of the present invention, methods are disclosed for the preparation of the medicaments described above for stimulating the growth of a hair bulb of a vellus hair follicle.

In yet another aspect of the present invention, methods are disclosed for stimulating the growth of a hair bulb of a vellus hair follicle that involves the topical administration of a therapeutic amount of the medicaments described above to a patient in need thereof.

In still further accordance with the teachings of the present invention, a composition for stimulating the growth of a hair bulb of a vellus hair follicle is disclosed. This composition includes either a secondary or tertiary amino local anesthetic or niacin as its active ingredient. This composition further includes a pharmaceutically-acceptable carrier.

Preferably, the carrier is a hydrophilic carrier that may be chosen from the group consisting of propylene glycol, lanolin, butyl alcohol, absolute alcohol, isopropyl alcohol and dimethyl sulfoxide. Alternatively, a combination of two or more of these carriers may be employed.

In another aspect of the present invention, there is disclosed a method of stimulating the growth of a hair bulb of a vellus hair follicle. This method includes: first, preparing a composition for stimulating the growth of a hair bulb of a vellus hair follicle which includes either niacin or a secondary or tertiary amino local anesthetic as its active ingredient, and a hydrophilic carrier; and second, topically applying the composition to a scalp having a vellus hair follicle in need thereof.

Brief Description of the Drawings

Figure 1 illustrates, in cross-section, a healthy terminal hair follicle.

Description of the Preferred Embodiments

With reference now to Figure 1, the hair follicle 10 includes a hair bulb 11 at the lower end thereof. The hair bulb 11 of the average mature hair follicle 10 lies approximately 0.5 - 4 mm below the stratum corneum of the epidermus.

Generally, and as referred to herein, the hair follicle is comprised of seven layers: the outer root sheath 12; Henle's layer 13; Huxley's layer 14; cuticle of inner root sheath 15; the cuticle of hair shaft 16; the cortex of hair shaft 17; and the medulla of hair shaft 18. Further as referred to herein, the base of the hair follicle comprises a hair bulb 11 which surrounds a dermal papilla 19. Above the dermal papilla 19 is a germative cellular layer 20 which is the active growth portion of the hair shaft 21.

It is believed that the dermal papilla 19 receives nutrients and oxygen, etc. from the vascular superficial plexus 22 (which, as used herein, includes the superficial plexus and capillaries thereof) and carries these nutrients and oxygen to the growing portion 20 of the hair bulb 11. While not precisely understood or agreed upon, it is believed that growth of the hair shaft 21 (and hence, scalp hair) is a consequence of this interaction. It is our further belief that the presence of various androgens, such as testosterone, including Dihydrotestosterone, can in certain genetically predisposed individuals, result in the development of non-terminal vellus hairs.

Also, while not precisely understood or agreed upon, the presence of these androgens is believed to be related to the presence in the hair bulb of various receptors which are sensitive therefor (which may or may not be genetically predetermined) and/or the presence of active androgens and their metabolities.

The causes of hair loss which are thought to from these factors include both scarring and non-scarring alopecia, specifically male and female pattern baldness, alopecia areata encompassing alopecia totalis and alopecia universalis. Additional non-scarring causes of alopecia which are thought to result from these factors include telogen and anagen effluvium. The scarring or cicatricial alopecias to be treated includes lichenplanopilaris, sarcoidosis, lupus erythematosus and other autoimmune diseases.

According to the teachings of the present invention, by increasing the vascular flow of oxygen and nutrients through the vascular plexus 22, the deleterious effect of the androgens can be superceded. This, it is believed, provides essential oxygen and nutrients to the cells of the germative cellular layer 20 and stimulates growth thereof resulting in the production of a terminal hair shaft 21 even in follicles 10 that had previously been vellus for numerous years.

The compositions and medicaments (therapeutic compounds) of the present invention utilize a powerful vasodilator, especially one having strong local effects, as an active ingredient. Also, a pharmaceutically-acceptable hydrophilic carrier is utilized as an adjunct. The preferred active ingredient is either a secondary or tertiary amino local anesthetic or niacin.

The preferred secondary and tertiary amino local anesthetics (active ingredient) are the esters of para-aminobenzoic acid which include chloroprocaine, buthethamine, naepaine and proparacaine. Especially preferred is procaine (which is also an ester of para-aminobenzoic acid) in the form of procaine hydrochloride (procaine HCL).

Alternatively, the preferred active ingredient may also be an amide including dibucaine, bupivacaine, lidocaine, mepivacaine and prilocaine.

Other local anesthetics of the secondary or tertiary amino type which have applicability in the present invention as an active ingredient are: esters of benzoic acid such as cocaine, piperocaine, hexylcaine, meprylcaine, benoxinate, propoxycaine and tetracaine: esters of meta-aminobenzoic acid, such as metabutethamine, isobucaine and cyclomethycaine: ethers such as pramoxine and dimethisoquin: the ketone dyclonine: and the phenetidin derivative phenacaine.

If desired, niacin may also be added to the active ingredient enumerated above.

The preferred pharmaceutically-acceptable carrier of the compositions and medicaments of the present invention is propylene glycol. While not preferred, other carriers such as lanolin, butyl alcohol, absolute alcohol (99% ethyl alcohol), isopropyl alcohol, and dimethyl sulfoxide (DMSO) may be employed either alternatively, or in combination therewith. Indeed, the preferred compositions and medicaments are comprised of from 50% to 95% of propylene glycol and 15% to 30% of absolute alcohol. Other hydrophilic solutions, ointments, creams or gels may also be employed.

One of the preferred compositions and medicaments useful in this practice is comprised of from .1 - 5% solution of procaine hydrochloride (with 2% being preferred) in a carrier solution comprised of 50 to 95% of propylene glycol (with 80% being preferred), .5 to 30% of ethyl (absolute) alcohol and .5 to 20% of water (with 10% being preferred). These compositions and medicaments may be .1 - 5% (with 2% being preferred) of Procaine Hydrochloride in "vehicle N". Vehicle N as defined herein is a composition comprised of 47.5% ethyl

alcohol, 4% isopropyl alcohol, purified water, Laureth-4 (a surfactant) and propylene glycol.

If desired, niacin may also be added to the compositions and medicaments noted above. While the amount of niacin to be added may range from 0.01 - 4% of the total composition or medicament, 0.1% is the preferred quantity.

Another of the preferred compositions and medicaments useful in this practice is comprised of a 0.01 - 4% solution of niacin (with 0.1% being preferred) in a carrier solution comprised of 50 to 95% of propylene glycol (with 80% being preferred), .5 to 30% of ethyl (absolute) alcohol and .5 to 20% of water (with 10% being preferred). These compositions and medicaments may be comprised of from 0.01 - 4% (with 0.1% being preferred) of niacin in "vehicle N". Vehicle N as defined herein is a composition comprised of 47.5% ethyl alcohol, 4% isopropyl alcohol, purified water, Laureth-4 (a surfactant) and propylene glycol.

The amount of niacin of the compositions and medicaments described above may range from 0.01 - 4% of the total composition or medicament, with 0.1% of niacin being the preferred quantity.

These compositions and medicaments are topically applied directly to a scalp in need thereof by use of a dropper, a porous applicator, a roll top, small brush or even by massaging in with the hands or any other means which is suitable for topical application which are well known to those skilled in the art. When a porous applicator is used, a microporous applicator is preferred.

The precise amount of the compositions and medicaments to be applied is within the skill of the art to determine. However, the amount applied would be that quantity necessary to thinly saturate the affected area of the skin. In this regard, the application of from 1/6 to 1/3 cc of the compositions or medicaments will be preferable. These topical applications are preferably performed one to two times daily. The frequency of these applications may be increased or decreased, as needed, as would be obvious to one skilled in the art

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will be substantially the same regardless of the type of alopecia being treated. Exact protocols are contemplated to vary from patient to patient depending on various factors, such as the medical health of the patient. Exact protocals to follow are well within the skill of the art to determine.

If desired, the compositions and medicaments may be incorporated in a shampoo or a gel form. In a shampoo, the compositions and medicaments include water, lauryl sulfate, a surfactant and, if desired, a fragrance. The shampoo is shaken prior to use to effect thorough mixing thereof and is hand-massaged into the scalp.

The invention will be more clearly perceived and better understood from the following specific examples.

[In each example, the proportions presented for the active ingredients, such as niacin or procaine HCL, are on a weight per unit volume basis (i.e. 5% procaine hydrochloride is 5 grams of procaine HCL per 100 cc of a pharmaceutically-acceptable topical carrier) and the proportions presented for the carrier consist of a percent by volume (i.e. 80% propylene glycol is 80 cc of propylene glycol per 100 cc of a pharmaceutically-acceptable topical carrier).]

Example One

A 2% solution of procaine hydrochloride in a propylene glycol carrier is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Two

A 0.1% solution of niacin in a propylene glycol carrier is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Three

A 2% solution of procaine hydrochloride in a carrier solution of 50 to 95% propylene glycol and 15 to 30% of absolute alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Four

A 0.1% solution of niacin in a carrier solution of 50 to 95% propylene glycol and 15 to 30% of absolute alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then

placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Five

A 2% solution of procaine hydrochloride in a carrier solution of 47.5% ethyl alcohol, 4% isopropyl alcohol, purified water, Laureth-4 (a surfactant) and propylene glycol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Six

A 0.1% solution of niacin in a carrier solution of 47.5% ethyl alcohol, 4% isopropyl alcohol, purified water, Laureth-4 (a surfactant) and propylene glycol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Seven

A 2% solution of procaine hydrochloride in a carrier solution of 80% propylene glycol, 10% water and ethyl (absolute) alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Eight

A 0.1% solution of niacin in a carrier solution of 80% propylene glycol, 10% water and ethyl (absolute) alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Nine

A 2% solution of procaine hydrochloride and 0.1% niacin in propylene glycol carrier is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is then placed in an eyedropper. The composition or medicament is then administered in a dropwise fashion on a portion of a human scalp in need thereof. Initially, the applications are made once every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Ten

A 2% solution of procaine hydrochloride in propylene glycol carrier is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Eleven

A 0.1% solution of niacin in a propylene glycol carrier is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Twelve

A 2% solution of procaine hydrochloride in a carrier solution of 50 to 95% propylene glycol and 15 to 30% of absolute alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted

area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Thirteen

A 0.1% solution of niacin in a carrier solution of 50 to 95% propylene glycol and 15 to 30% of absolute alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Fourteen

A 2% solution of procaine hydrochloride in a carrier solution of 47.5% ethyl alcohol, 4% isopropyl alcohol, purified water, Laureth-4 (a surfactant or pharmaceutically acceptable carrier) and propylene glycol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Fifteen

A 0.1% solution of niacin in a carrier solution of 47.5% ethyl alcohol, 4% isopropyl alcohol, purified water, Laureth-4 (a surfactant or pharmaceutically acceptable carrier) and propylene glycol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Sixteen

A 2% solution of procaine hydrochloride in a carrier solution of 80% propylene glycol, 10% water and ethyl (absolute) alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Seventeen

A 0.1% solution of niacin in a carrier solution of 80% propylene glycol, 10% water and ethyl (absolute) alcohol is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Example Eighteen

A 2% solution of procaine hydrochloride and 0.1% niacin in a propylene glycol carrier is prepared. Approximately 1/6 to 1/3 cc of this composition or medicament is placed in a container having a microporous applicator. This composition or medicament is then administered by application through the microporous applicator, so as to thinly saturate the afflicted area of the human scalp in need thereof. Initially, these applications are made every twelve hours. Eventually, the frequency of these applications may thereafter be decreased (or increased) as needed.

Obviously, many modifications may be made without departing from the basic spirit of the present invention. Accordingly, it will be appreciated by those skilled in the art, that within the scope of the appended claims, the invention may be practiced other than has been specifically described herein.

Claims

1. The use of a secondary or a tertiary amino local anesthetic for the manufacture of a topical medicament for stimulating the growth of a hair bulb of a vellus hair follicle.

2. The use of claim 1, further characterized in that the anesthetic is a secondary or tertiary

amino ester of para-aminobenzoic acid.

3. The use of claim 2, further characterized in that the ester is chosen from the group consisting of procaine hydrochloride, chloroprocaine, buthethamine, naepaine and proparacaine.

4. The use of claim 1, further characterized in that the anesthetic is a secondary or tertiary amino ester of benzoic acid.

5. The use of claim 4, further characterized in that the ester is chosen from the group consisting of cocaine, piperocaine, hexylcaine, meprylcaine, benoxinate, propoxycaine and tetracaine.

6. The use of claim 1, further characterized in that the anesthetic is a secondary or tertiary amino ester of meta-aminobenzoic acid.

7. The use of claim 6, further characterized in that the ester is chosen from the group consisting of meta-butethamine, isobucaine and cyclomethycaine.

8. The use of claim 1, further characterized in that the anesthetic is a secondary or tertiary amino type amide.

9. The use of claim 8, further characterized in that the amide is chosen from the group consisting of dibucaine, bupivacaine, lidocaine and prilocaine.

10. The use of claim 1, further characterized in that the anesthetic is a secondary or tertiary amino type ether.

11. The use of claim 10, further characterized in that the ether is chosen from the group consisting of pramoxine and dimethisoquin.

12. The use of claim 1, further characterized in that the anesthetic is a secondary or tertiary amino type ketone.

13. The use of claim 12, further characterized in that the ketone is chosen from the group consisting of dyclonine and phenacaine.

14. The use of claim 1, further characterized in that the composition of claim 1 is combined with a pharmaceutically-acceptable carrier for the manufacture of the medicament.

15. The use of claim 14, further characterized in that the carrier is chosen from the group consisting of propylene glycol, lanolin, butyl alcohol, absolute alcohol, isopropyl alcohol and dimethyl sulfoxide.

16. The use of niacin for the manufacture of a topical medicament for stimulating the growth of a hair bulb of a vellus hair follicle.

17. The use of claim 16, further characterized in that the composition of claim 16 is combined with a pharmaceutically-acceptable carrier for the manufacture of the medicament.

18. A method for the preparation of a medicament for stimulating the growth of a hair bulb of a vellus hair follicle characterized in that the composition of either of claims 1 or 16 is combined with a pharmaceutically-acceptable carrier.

19. A method for stimulating the growth of a hair bulb of a vellus hair follicle characterized in that a therapeutic amount of the medicament of either of claims 1 or 16 is topically administered to a patient in need thereof.

20. A composition for stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the composition, characterized by:

niacin for growth stimulation;

procaine hydrochloride for growth stimulation; and

a pharmaceutically-acceptable carrier for penetrating the scalp and for carrying the niacin and procaine hydrochloride therewith.

21. The composition of claim 20, further characterized in that the pharmaceutically-acceptable carrier is propylene glocol.

22. The composition of claim 20, further characterized in that the composition includes absolute alcohol and water.

23. The composition of claim 20, further characterized in that the composition includes isopropyl alcohol and water.

24. A composition for stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the composition characterized by:

0.01% - 4% by weight per unit volume of niacin for growth stimulation; and

a pharmaceutically-acceptable carrier for penetrating the scalp and for carrying the niacin therewith.

25. The composition of claim 24, further characterized in that the carrier includes 50% - 95% by volume of propylene glycol, .5% - 30% by volume of absolute alcohol, and .5% - 20% by volume of water.

26. A composition for stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the composition characterized by:

niacin for growth stimulation and a pharmaceutically-acceptable carrier for penetrating the scalp and for carrying the niacin therewith, the carrier including ethyl alcohol, isopropyl alcohol, purified water, Laureth-4 and propylene glycol.

27. A method for stimulating the growth of a hair bulb of a vellus hair follicle of a scalp, the method characterized by the steps of:

preparing a composition including niacin and a pharmaceutically-acceptable hydrophilic carrier; and

applying topically the composition to a scalp having at least one vellus hair follicle in need thereof for stimulating the growth thereof.

28. The method of claim 27, further characterized in that the composition is topically applied thinly saturating the afflicted area of the scalp in need thereof.

29. The method of claim 27, further characterized by placing in a topical applicator a quantity of the composition necessary to thinly saturate the afflicted area of the scalp in need thereof; and wherein the composition is topically applied, thinly saturating the afflicted area of the scalp in need thereof.

30. The method of claim 29, further characterized in that the topical applicator is a microporous applicator.

31. The method of claim 29, further characterized in that the topical applicator is a roll top applicator.

32. The method of claim 29, further characterized in that the topical applicator is an eyedropper.

33. The method of claim 29, further characterized in that the composition is topically applied to the scalp in a dropwise fashion.

34. A method of stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the method characterized by the steps of:

preparing a composition of 0.01% - 4% by weight per unit volume of niacin for growth stimulation, and a pharmaceutically-acceptable carrier for penetrating the scalp and for carrying the niacin therewith, the carrier including 50% - 95% by volume of propylene glycol, .5% - 30% by volume of absolute alcohol and .5% - 20% by volume of water; and

topically applying the composition to a scalp having at least one vellus hair follicle in need thereof for stimulating the growth thereof.

35. A composition for stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the composition characterized by:

niacin;

procaine hydrochloride; and

propylene glycol.

36. A method for stimulating growth of a hair bulb of a vellus hair follicle characterized by the steps of:

preparing a composition having niacin and a pharmaceutically-acceptable hydrophilic carrier; and

applying topically the composition to a scalp having at least one vellus hair follicle in need thereof.

37. A composition for stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the composition characterized by:

procaine hydrochloride and niacin for growth stimulation; and

a pharmaceutically-acceptable carrier for penetrating the scalp and for carrying the niacin and procaine hydrochloride therewith.

38. A composition for stimulating growth of a hair bulb of a vellus hair follicle of a scalp, the composition characterized by:

niacin; and

propylene glycol.

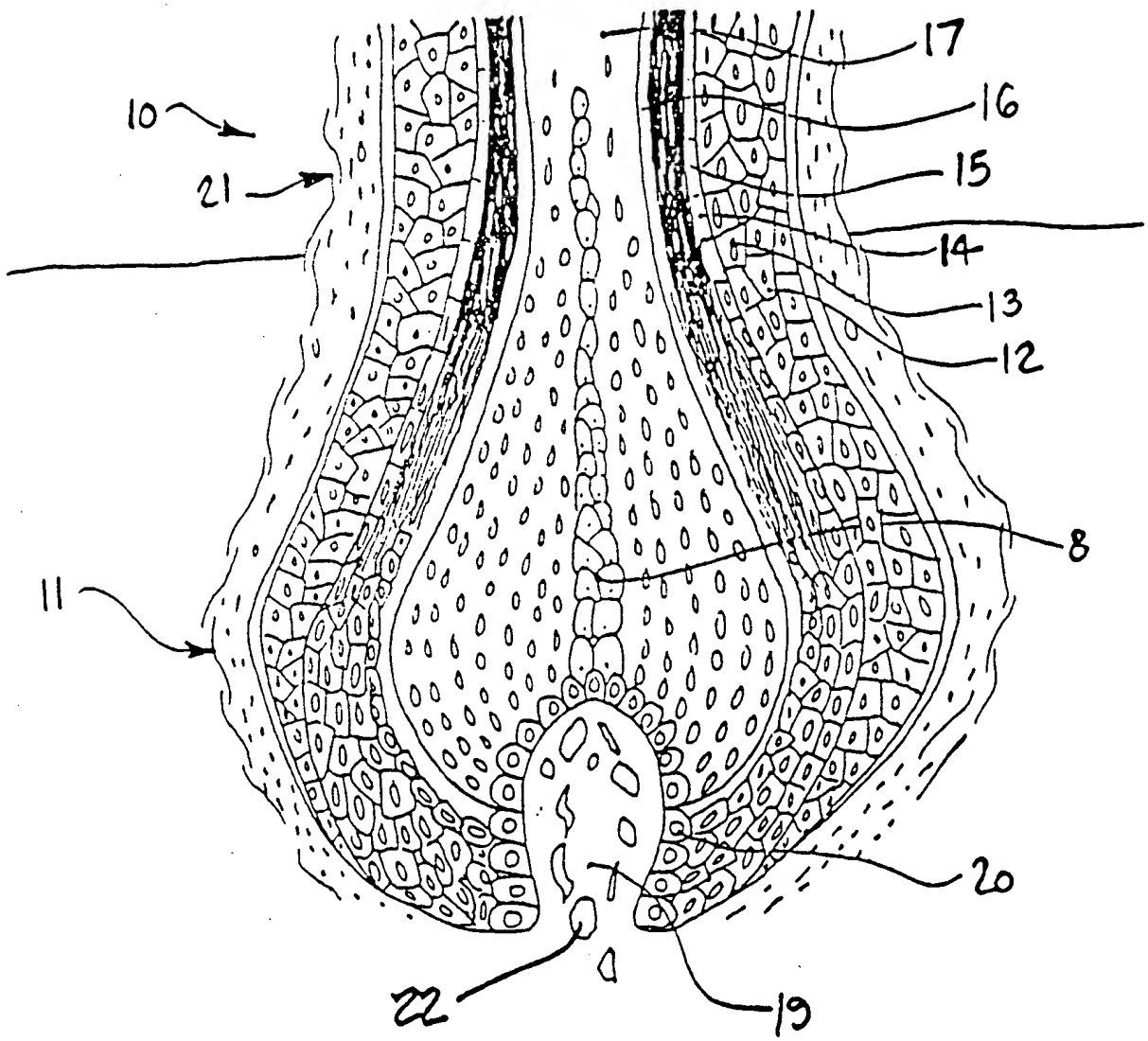

Fig. 1

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 471 135 A3**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **90870129.5**

(51) Int. Cl.5: **A61K 7/06**

(22) Date of filing: **14.08.90**

(43) Date of publication of application:
19.02.92 Bulletin 92/08

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(88) Date of deferred publication of the search report:
18.03.92 Bulletin 92/12

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(57) Compositions, medicaments and methods for the promotion of hair growth are disclosed. These compositions and medicaments are comprised of either local anesthetics of the secondary or tertiary amino type or niacin. The preferred secondary and tertiary amino compounds include those which are esters of para-aminobenzoic acid, esters of Benzoic acid, esters of meta-amino benzoic acid, amides, ethers, and ketones. The preferred compositions and medicaments include either procaine hydrochloride or niacin in a propylene glycol carrier. The disclosed compositions and medicaments may be topically applied to a scalp in need thereof by an eyedropper or other suitable means.

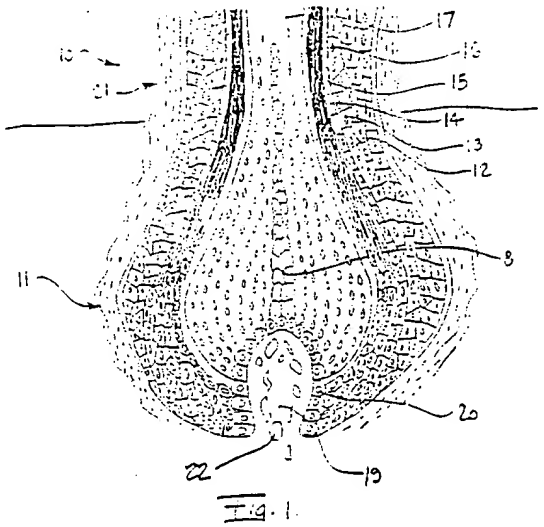

Fig. 1

EP 0 471 135 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 90 87 0129

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	GB-A-2 177 919 (AWS SHAKIR MUSTAFA SALIM) * Page 1, right-hand column, lines 69-74; page 2, right-hand column, lines 85-90; examples 1,2,9; claims 1,7,8,11-13,15,16 *	1-5,14-15	A 61 K 7/06
X	FR-A-1 439 833 (P. SERVIERE) * Whole document *	1-3	
X	FR-A- 336 814 (U. ASCOLI) * Whole document *	1,4-5	
X	EP-A-0 158 090 (ISMAIL ROSHDY) * Page 4; page 6, line 11; page 7, lines 9-20; example 22; claims 1,8,10,11 *	1-3,14-15,20	
X	FR-A-2 159 400 (INDAL OY) * Whole document *	16-19, 24,27, 36	TECHNICAL FIELDS SEARCHED (Int. Cl.5)
X	GB-A-2 176 104 (J.-F. GROLLIER et al.) * Whole document *	16-19, 24,27-29,36	A 61 K

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	09-07-1991	SIERRA GONZALEZ M.T.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims 1-15,18-23,35,37: Amino local anesthetic for stimulating the hair growth.

2. Claims 16-19,24-34,36,38: Niacin for stimulating the hair growth.

European Patent Office

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CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid,

namely claims:

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions,
namely:

See sheet -B-

☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid,

namely claims:

☐ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims,

namely claims: